

**California Health and Human Services Agency
Committee for the Protection of Human Subjects**

CONTINUING PROJECT REVIEW FORM—HUMAN SUBJECTS CONTACT

PROJECT NO.: _____ **PI (please print):** _____
Last First

PROJECT TITLE: _____

Please respond to the following issues and questions:

1. Status of project:
☐ **Continuing** -Please attach any findings to date and include a copy of all publications.
☐ **Completed** -Please attach any findings to date and include a copy of all publications.
☐ **Withdrawn** -Please provide in the cover letter an explanation of why the project is being withdrawn.
☐ **HIPAA** waiver or alteration of authorization requested
-Please include in the cover letter a statement as to whether there have been any changes in data security practices or other factors that might be relevant to the continuing of the waiver.
2. Has the involvement of human subjects permanently ended? This includes contact, enrollment, and interventions?
☐ **Yes** ☐ **No**
3. Have any complaints, verbal or written, been received from study participants?
☐ **Yes** ☐ **No**
(If “Yes,” attach a copy and description of details.)
4. Have there been any adverse events?
☐ **Yes** ☐ **No**
(If “Yes,” attach a **detailed** explanation.)
5. Have there been any breeches of data security?
☐ **Yes** ☐ **No**
(If “Yes,” attach a **detailed** explanation.)
6. Have any difficulties been experienced during the research or have there been any unanticipated problems?
☐ **Yes** ☐ **No**
(If “yes,” attach a **detailed** explanation.)
7. Are you requesting any changes to your approved protocol?
☐ **Yes** ☐ **No**
(If “yes,” please attach copies of old protocol with tracked changes and clean copies of new protocol with original signatures from PI and responsible official.)
8. Are you proposing any changes to other project documents or materials (e.g., consent forms, survey instruments, questionnaires, etc.)?
☐ **Yes** ☐ **No**
(If “yes,” please attach old materials with tracked changes and clean copies of new materials and ensure protocol reflects changes, as appropriate.)
9. Are you requesting a change in P.I.?
☐ **Yes** ☐ **No**
(If “Yes,” in the cover letter give name of old and new or additional P.I. If new PI is being added, address conflict of interest questions in #12 of the CPHS protocol in cover letter.)

10. Date subject enrollment began: _____ Number of proposed subjects: _____
- A. Total number of subjects enrolled since project began (active and inactive): _____
- B. Number of subjects currently enrolled in project: _____
- C. Number of subjects offered enrollment in past year: _____
- D. Number of subjects who declined enrollment in the past year: _____
- E. Total number of subjects withdrawn since project began (attach reasons): _____
- F. Number of subjects expected to enroll in coming year: _____
- G. Expected total number in project: _____
- H. Expected completion date of project: _____

11. List the formal names of any California Health and Human Services Agency (CHHSA) databases, such as the Cancer Registry, to be used in this project.

Department	Name of Database(s)
Dept. of Health Services	
Office of Statewide Health Planning and Development	
Dept. of Mental Health	
Dept. of Developmental Services	
Dept. of Social Services	
*	
*	

12. Check the box(es) which indicates the nature of each CHHSA department's involvement – e.g., Funding (pass through or source of funding), principal investigator (PI), research staff involved (staff), or supplying human subjects (note that **only** subjects for which the State has direct responsibility, e.g., mental hospital patients should be included.). *Specify any other CHHSA departments involved.

Department	Funding	PI	Staff	Subjects
DHS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
OSHPD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DMH	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DDS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DSS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* Specify other department(s) involved.

Signature of P.I.: _____ Date: _____

P.I.'s Phone Number: _____

E-mail: _____

Address: _____

Other Contact Person (if applicable):

Name: _____
Last First

Title: _____

Phone Number: _____

Email: _____